

### **Remarks/Arguments**

According to the Advisory Action mailed on November 4, 2004, Applicants' reply to the final Office Action of April 19, 2004 was not entered, since the "claims as proposed in the after final amendment appear to be a standard, routine assay for measuring the affinity of an antagonist of a ligand-receptor interaction and include limitations not previously examiner, which would necessitate further consideration and search."

The present Preliminary Amendment serves to replace the unentered amendment filed on October 18, 2004. All amendments are of formal nature and serve to address issues of alleged ambiguity raised in the final Office Action mailed on April 19, 2004 (Confirmation No. 7564). The amendments do not introduce new matter.

The Examiner is respectfully consider the following arguments before any further action on this application.

### **Interview Summary Record**

The undersigned attorney thanks the Examiner for the opportunity to briefly discuss this application during a telephone interview on November 12, 2004. During the interview, the Advisory Action of November 4, 2004 was discussed, and it was agreed that Applicants would file a Request for Continued Examination, in order to enable the Examiner to consider new issues raised by the claim amendments presented in Applicants' after final response.

### **The Office Action of April 19, 2004**

#### ***Claim Rejections - 35 USC § 112***

(1) Claims 1 and 2 were rejected under 35 USC § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While the Examiner acknowledged that the amendments made in response to the previous Office Action helped alleviating problems with the antecedent basis for the terms in the claims, the claims remained rejected as being indefinite for the following reasons:

(i) claims 1 and 2 omitted the step or the addition of the serially diluted phagemid clone;

(ii) it was unclear “how binding of the phagemid clone to the ligand is inhibited by the phagemid clone and how this inhibition is measured when, according to [the] claimed method, only a phagemid clone, a polypeptide, and a ligand are present.”

The claims as currently amended clearly describe that the claimed assay is based on measuring the degree to which binding of a phagemid clone displaying a peptide to a ligand is inhibited by a polypeptide which competes with the peptide for ligand binding, at low and high phagemid concentrations. As described in Example 7 (page 11, line 13 - page 112, line 31), and as clearly recited in the amended claims, phagemid clones whose binding to the ligand is inhibited by the polypeptide only at low phagemid concentrations have a higher affinity for the ligand than phagemid clones the binding of which is inhibited at both high and low phagemid concentrations, and the degree to which binding of the phagemid clone to the ligand is inhibited by the polypeptide determines the relative binding affinity of the peptide displayed on the phagemid to the ligand.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

(2) Claims 1 and 2 were additionally rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner noted that despite Applicants’ prior arguments, it “doesn’t matter whether the ‘phage’ is the same as or different from the ‘phagemid.’ In either case, it would be impossible for the ‘phage’ to inhibit ‘only at low concentrations’ and not a higher phagemid concentrations.” Applicants believe that the current rewording of claim 1 obviates this rejection. Claim 1 is now clear in stating that the assay measures the degree to which a polypeptide, competing for ligand binding, inhibits the binding of phagemid clones to the ligand, at high and low phagemid concentrations. As described in Example 7, and shown in Figures 26-28, this method is fully operable and yields the information (relative binding affinity) recited in the claims.

Accordingly, Applicants respectfully request the withdrawal of this rejection.

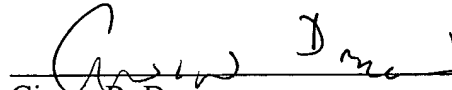
All claims pending in this application are believed to be in prima facie condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39766-0127P1D15).

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: November 16, 2004

  
Ginger R. Dreger  
Reg. No. 33,055

**HELLER EHRMAN WHITE & McAULIFFE LLP**

**Customer No. 25213**

275 Middlefield Road

Menlo Park, California 94025

Telephone: (650) 324-7000

Facsimile: (650) 324-0638

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HELLER EHRMAN WHITE & MCAULIFFE LLP  
275 MIDDLEFIELD ROAD  
MENLO PARK, CO 94025-3506

EXAMINER

ROMEO, DAVID S

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1647

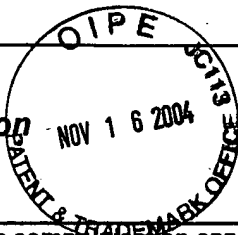
DATE MAILED: 11/04/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

PREVIOUSLY DOCKETED

APPEAL BRIEF  
DNE - 12/18/04  
FINAL - 5/18/05

**Advisory Action**

Application No.

09/724,481

Applicant(s)

CLARK ET AL.

Examiner

David S Romeo

Art Unit

1647

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 October 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 18 October 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1 and 2.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

David S Romeo  
Primary Examiner  
Art Unit: 1647

009/724,481

Continuation of 2. NOTE: the claims before the proposed after final amendment recite "measuring the degree to which binding of the phagemid clone to the ligand is inhibited by the peptide displayed on said phagemid clone" and "ligand is inhibited by the peptide." If the proposed after final amendment had been entered the claims would recite "measuring the degree to which binding of the phagemid clone to the ligand is inhibited by the polypeptide" and "ligand is inhibited by the polypeptide." The claims as proposed in the after final amendment appear to be a standard, routine assay for measuring the affinity of an antagonist of a ligand-receptor interaction and include limitations not previously examined, which would necessitate further consideration and search.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments are directed to the newly proposed or amended claims and that amendment has not been entered..